

IN RE: Bard IVC Filters Products Liability Litigation
No. 2:15-MD-02641-DGC

EXHIBIT A

Christopher S. Morris, MD

Bard IVC Filter Class Action
Expert Report

Personal Background and Experience

I am an Interventional Radiologist with over 25 years of clinical experience at a busy tertiary care referral center. This includes the placement and retrieval of inferior vena cava filters (IVCFs), as well as the care and management of patients with IVCFs. I graduated from Case Western Reserve University School of Medicine in 1985 and completed an Internship in Internal Medicine at Cleveland Metropolitan General Hospital. My residency in Diagnostic Radiology was obtained at the Ohio State University Hospitals from 1986 to 1990 and my fellowship in Vascular and Interventional Radiology was obtained at the Massachusetts General Hospital from 1990 to 1991. My residency and fellowship were heavily weighted towards IVCFs. I trained with leaders in the field, including some of the first Interventional Radiologists, Drs. Vanaman and Stockum, to place Greenfield IVCFs percutaneously, which revolutionized the practice of IVCF insertion more than 30 years ago. Ohio State University Hospitals has a long tradition of innovation in Interventional Radiology, which stimulated my interest in this specialty. Drs. Vanaman and Stockum were trained by Dr. William Molnar, a Grandfather of Interventional Radiology who was instrumental in developing the technique of coronary and cardiac angiography, as well as long term percutaneous biliary drainage. A Founding Fellow of the Society of Cardiovascular and Interventional Radiology, Dr. Molnar was an emeritus Professor of Radiology who taught me during the early part of my residency. At Massachusetts General Hospital, I trained with Drs. Waltman and Athanasoulis, who are also distinguished Interventional Radiologists and experts in the field of IVCFs.

I serve as a Professor of Radiology and Surgery at the Robert Larner, MD College of Medicine at the University of Vermont, and teach residents, fellows, and medical students about IVCFs, including indications, contraindications, risks, and complications of IVCFs, as well as alternative therapies for venous thromboembolic disease. During this timeframe, I have taught more than 100 residents in Diagnostic Radiology as they rotated on the Interventional Radiology service, in addition to 28 fellows in Interventional Radiology, who worked closely with me on a daily basis. I co-founded the Fellowship in Interventional Radiology at the University of Vermont in 1994 and have served as the Program Director for the Diagnostic Radiology Residency, as well as the Fellowship in Interventional Radiology.

I also taught Interventional Radiology colleagues about IVCFs as a member of the IVCF Workshop series during the annual national meeting of the Society of Interventional Radiology for five years, during the introduction of optional IVCFs in the United States. I was the chair of this Workshop series for three years.

the heart and causing the death of the patient. He then states that no similar cases have been reported with the predicate Bard Simon Nitinol IVCf. However, several years after the availability of the Bard Simon Nitinol IVCf, two cases of migration to the chest, one that transited the heart and ended up in the pulmonary artery, and the other to the heart, were published (73).

Dr. Eisenberg attributes several opinions to Dr. Betensky in paragraph 111. They omit the fact that real world follow up (outside of research studies) was dramatically increased with optional IVCfs, compared to permanent IVCfs. As an Interventional Radiologist, I can attest to the fact that many patients with permanent IVCfs were not followed, since we never made any effort to track these patients and look for asymptomatic complications such as perforation, fracture, tilt, and migration. With the advent of optional IVCfs, patients began to be tracked. In those patients whose IVCfs were retrieved, intensive digital fluoroscopic and angiographic imaging occurred during IVCf retrieval attempts, providing a new opportunity to evaluate asymptomatic IVCfs. This phenomenon did not occur with permanent (non optional) IVCfs. This pattern could have contributed to the larger number of IVCf complications submitted voluntarily to the MAUDE database during this time-frame of the Bard Recovery and G2 IVCfs. No permanent IVCf was clinically investigated and imaged, on a global scale, to the same degree as the optional IVCfs. Once complications of optional IVCfs were found and widely publicized, Interventional Radiologists began looking more closely for these complications in their own patients, which resulted in more submissions to the MAUDE database and the desire to be the “first” to publish complications of the new IVCfs. Therefore, some element of the “notoriety effect” did occur, contrary to the opinion of Drs. Betensky and Eisenberg. Finally, confounding variables and channeling bias did occur with the bariatric population. Permanent IVCfs with the prophylactic indication were not placed to any significant degree into bariatric patients. However, many bariatric surgeons believed that an optional IVCf was a good solution to the high rate of perioperative pulmonary embolism deaths in their patient population, since the IVCf could be retrieved once their patient became ambulatory and free of pulmonary embolism risk. As we all know, bariatric patients are at a higher risk of many complications due to their morbid obesity, such as post operative infections, cardiovascular disease, and thromboembolic disease, and therefore will be associated with a higher morbidity and mortality than non obese patients.

Expert Report of Dr. Bates

I have read the Expert Report of Dr. Bates. I believe that he may be confusing medical screening with the one-time imaging test associated with the “medical monitoring” proposal for all patients with a Bard optional IVCf. Since medical imaging is a “snap shot” of the area of interest at a point in time, it must be repeated periodically over time to be considered a screening test for a disease or abnormality that is acquired. A one-time CT scan to detect acquired abnormalities of an optional IVCf does not meet this criterion and should not be confused with a screening test. An annual CT scan of the abdomen and pelvis would be a very aggressive strategy to detect an acquired abnormality with the IVCf. For example, another medical